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EXAMINER

WELLS, LAUREN Q

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 09/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/859,384

Applicant(s)

NONOTTE ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Claims 1-21 are pending.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 09/859,392. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a method of topically, orally, or injectably administering a composition comprising manganese.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 and 7-14, 17-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the reduction of wrinkles, does not reasonably provide enablement for preventing wrinkles. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

The disclosure of the present invention is directed to a method of reducing wrinkles as set forth in independent claims 1-7, 15 and 21. A skilled practitioner in the art using the teachings of Riley et al. (5,925,348) would be motivated to use manganese ions/salts to reduce or eliminate wrinkles. However, preventing wrinkles is inconsistent with what is known in the art since (1) reduction of wrinkles indicates that hair loss is decreased, but not prevented; and (2) elimination of wrinkles indicates that symptoms of wrinkles may occur. Furthermore, prevention of wrinkles indicates that the subject never experiences any characteristics associated with wrinkles. Hence, the amount of guidance present in the specification, the absence of data indicating that the symptoms of wrinkles do not occur when manganese carried in composition is administered, and

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the state of the prior art indicating that the treatment using manganese in composition is possible, all indicate that treatment, not prevention of wrinkles is possible.

The amount of guidance necessary to perform Applicant's invention would result in undue experimentation because the skilled artisan would be forced to randomly test numerous conditions and amounts of manganese in composition to determine what manganese composition prevents hair loss. Hence, the amount of guidance present in the specification fails to present the necessary instruction such that one can readily determine the appropriate composition of claims 2 and 7-14, 17-20.

Note: The Examiner reviewed Applicant's specification, but noted that the data does not indicate prevention of wrinkles.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 10, 15, 16, 19 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The terms "slackening" and "relaxing" in claims 1 (line 1), 6 (line 1), 7 (line 7), 15 (line 1), 16 (line 1), 21 (line 2) are vague and indefinite, as it is not clear what physical properties these terms are referring to. What are the physical or chemical signs of slackening and relaxing?

(ii) The term "curatively treating wrinkles" in claim 2 (line 1) is vague and indefinite, as it is not clear what physical properties this term refers to. What are the physical signs of curatively treating wrinkles?

(iii) The term "thus-effective" in claims 1-7, 15, 16 is vague and indefinite, as it is not clear what a "thus-effective" amount is. Deleting the term "thus" would overcome this rejection.

(iv) The term “muscularly relaxing” in claim 6 is vague and indefinite, as it is not clear what physical properties this term refers to. How does cutaneous or subcutaneous tissue muscularly relax?

(v) The term “microrelief” in claims 5 (line 1), 7 (line 4) is vague and indefinite, as it is not clear what this term means. The specification does not further define this phrase and one of ordinary skill in the art would not be apprised of it.

(vi) The term “manganese-rich” in claim 10 (line 3) is vague and indefinite, as it is not clear what this means. How is an extract rich in manganese? Does this mean that manganese is being added to the extract? What does this mean?

(vii) Claim 19 is vague and indefinite, as it is confusing. Should there be an “is” between “composition” and “a” on line 2? Are not gels, emulsions, creams, oils, milks, makeup, serums, aerosols, vesicular dispersions, and artificial tanning preparations all topically applicable solutions?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

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(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1-7, 15, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Thorel (FR 2612775).

Thorel teaches a composition for controlling degeneration of skin comprising manganese, vitamin A, ascorbic acid, and bilberry extract. The composition is especially used to control the aging process. See entire abstract.

Claims 1-11, 13-16, 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Okaya et al. (EP 0424033).

Okaya et al. teach an external skin preparation for combating skin-roughening. Disclosed is a skin lotion comprising 0.1% manganese chloride in a aqueous vehicle. See abstract; pg. 3. lines 42-47; pg. 4, line 1-pg. 8, line 58.

Claims 1-17, 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Hahn et al. (WO 96/19182).

Hahn et al. teach compositions and methods for reducing skin irritation. The composition comprising a topical vehicle, an irritant ingredient, and an anti-irritant amount of one or more aqueous soluble cations, wherein manganese cations is one of the cations. Alpha-hydroxy acids and retinoids are disclosed as irritants. Creams, lotions, and moisturizers are disclosed as cosmetic forms. Topical and oral administration are disclosed. Nitrate, sulfate, borate, phosphate, gluconate, carbonate, acetate, citrate, oleate, and oxalate are disclosed as counteranions to the cations. Injections forms of the composition are further disclosed. See pg. 28; pg. 37-48.

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Claims 1-7, 10-11, 14-16, 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Sanders et al. (5,895,642).

Sanders et al. teach a topical composition comprising a complex of ions of a transition metal, bicarbonate ions, and a chelating agent in a cream vehicle. Manganese is disclosed as the transition metal. Disclosed is a method of topically administering the composition. See Col. 7, line 10-Col. 8, line 45.

Claims 1-11, 13-16, 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Brenton et al. (5,900,257).

Brenton et al. teach a topical skin composition comprising 5% manganese borate and 0.05% retinoid acid in an aqueous vehicle. See Col. 4, lines 51-Col. 5, line 63; Col. 9, line 24-Col. 12, line 56.

Claims 1-7, 10-11, 15, 17, 20-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Riley et al. (5,925,348).

Riley et al. teach methods utilizing compositions containing sacred lotus to treat aging skin. Disclosed is a dietary supplement comprising vitamin A palmitate and magnesium stearate in a carrier. The composition is disclosed in the form of a pill.

Claims 1-7, 10, 14, 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaneko (JP 09157128).

Kaneko teaches a cosmetic material for aging comprising metal ions, wherein manganese is disclosed as an ion. See abstract.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn et al.

Hahn et al. is applied as discussed above. The reference lacks an exemplification of injectable compositions.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to exemplify the composition of Hahn et al. as being administered by injection because Hahn et al. teach that their compositions can be administered by injection.

Claims 7, 10, 11, 12, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brenton et al.

Brenton et al. is applied as discussed above. Further, the reference teaches borates, chlorides, nitrates, acetates, oleates, and others as salts for manganese, and teaches oral and injectable administration. The reference lacks exemplification of preferred manganese salts and injectable and oral administration.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to exemplify the preferred manganese salts and injectable and oral administration using the teachings of Brenton et al., because Brenton et al. teaches that manganese can take the

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form of the preferred salts in their composition, and teaches injectable, oral, and topical administration as interchangeable.

Unexpected Results

It is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

In the instant case, there are no unexpected results.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

RUSSELL TRAVERS
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